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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,606	10/11/2000	Enrique J. Klein	020460 000710US	2574

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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/687,606

Applicant(s)

KLEIN, ENRIQUE J.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 07, 2003 has been entered.

### ***Claim Objections***

Claim 4 is objected as being in improper form because a multiple dependent claim. Accordingly, claim 4 refers back to the radiopaque material that has not been claimed in claim 1. In order to properly claim a multiple dependent claims all the structure limitations have to have in the previous claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Lashinski et al US Patent 6,071,296.

Lashinski et al discloses a stent (51) comprising a cylindrical frame having a distal end, a proximal end, a midsection and an outer surface (see Fig. 5A). The frame is formed from material comprising radiolucent material (see col. 2, lines 66-67; col. 3, lines 66-67; col. 4, lines 1-6; col. 4, lines 45-50; col. 3, lines 11-26 and col. 4, lines 64-67, see explanation below) wherein the forming material varies in thickness over an axial length of the cylindrical frame (54), so that the radiopacity varies correspondingly. Additionally, the stent is thicker near the ends (see Fig. 5A and col. 4, lines 64-67 and col. 5, lines 1-5).

Regarding claim 5, see col. 5, lines 65-66 and col. 6, lines 1-5 disclosing more material at the end of the stent in order to accurately place the stent within the blood vessel. Regarding the last three sentences of claim 5, if the end regions are thicker than the rest of the stent then the rest of the stent will be more radiolucent.

The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974).

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt US Patent 5,824,045.

Alt discloses a stent (10) comprising a cylindrical frame having a distal end (35), a proximal end (36), a midsection and an outer surface (see Fig. 1A). The frame is formed from material comprising radiolucent material (stainless steel, see col. 4, lines 52-57) wherein the

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forming material varies in thickness over an axial length of the cylindrical frame (see col. 5, lines 16-23), so that the radiopacity varies correspondingly. Additionally, the stainless steel material is coated with gold (see col. 5, lines 46-58).

Regarding claim 7, line 4, the Examiner interpreted the frame as the structure that varies in thickness.

The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974).

***Response to Amendment***

Applicant's arguments filed July 03, 2003 with respect to the Lashinski et al reference have been fully considered but they are not persuasive.

The Lashinski et al reference discloses a stent that is preferably made of radiopaque material (see col. 5, lines 63-65). However, the Lashinski et al reference clearly discloses a stent that can be made of metal or non-metal (see col. 4, lines 64-67) and nowhere discloses a stent made out of gold, platinum, tantalum, etc. It is well known in the art the use of any kind of metal, such as stainless steel, titanium, Nitinol, etc. Additionally, Lashinski et al discloses a plurality of stents that can be used by balloon expansion, self-expansion, etc (see col. 3, lines 20-23). Therefore, if the stent is a self-expandable device (e.g. Nitinol) then the stent is a radiolucent material. Finally, the method and apparatus of the Lashinski et al reference is illustratively described with respect to the stainless steel stent structure described in the US Patent 4,733,665 (see col. 1, lines 66-67; col. 3, lines 66-67; and col. 4, lines 1-2). For the above reasons, the stent is capable of being made of stainless steel or any other radiolucent material.

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The word "radiopaque" in claim 4 is not well defined, therefore, the Examiner interpreted claim 4 broad. Claim 4 is a multi-dependent claim that depends on claim 1. Claim 1 does not show support of the word "radiopaque". Therefore, the Examiner has interpreted the word "radiopaque" as a material than stop the passage of x-rays, thus, it is well known in the art that if the thickness of any metallic radiolucent material (e.g. stainless steel, titanium, Nitinol, etc) is increased, then the stent will be capable of being radiopaque. For that reason, the Lashinski et al reference discloses in col. 5, lines 63-66 and col. 6, lines 1-5 a stent having more material at the end regions of the stents in order to increased the visibility of the stent during the deployment steps. Finally, the Lashinski et al reference discloses added material (54) that may have the same composition of the stent or alternatively may have a different composition. For example, the added material can be a metal or a non-metal (see col. 4, lines 64-67).

Note: if the Applicant wants to overcome the rejection to claim 4, claim 4 has to depend only on claims 2 and 3.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Alvin Stewart', with a stylized flourish at the end.

Alvin Stewart  
July 23, 2003